

### **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listings of claims in the application.

Claim 1 (Currently Amended): An implantable device for administration of a dopamine agonist to a mammal in need thereof, comprising a dopamine agonist that binds to one or more dopamine receptor subgroups and a biocompatible, nonerodible polymeric matrix,

wherein said dopamine agonist is encapsulated within said matrix,

wherein the implantable device is produced by an extrusion process,

wherein the implantable device is uncoated, and

wherein when said implantable device is implanted subcutaneously in said mammal, said dopamine agonist is continuously released *in vivo* over a sustained period of time through pores that open to the surface of said matrix at a rate that results in a steady state plasma level of at least about 0.01 ng/ml [[at steady state]] for the sustained period of time.

Claim 2 (Original): An implantable device according to claim 1, wherein the polymeric matrix comprises ethylene vinyl acetate copolymer (EVA).

Claim 3 (Original): An implantable device according to claim 2, wherein said EVA comprises about 33% vinyl acetate.

Claim 4 (Original): An implantable device according to claim 1, comprising about 10 to about 85% dopamine agonist.

Claim 5 (Previously presented): An implantable device according to claim 1, wherein said dopamine agonist is selected from the group consisting of apomorphine, lisuride, pergolide, bromocriptine, pramipexole, ropinerole, and rotigotine.

Claim 6 (Withdrawn): An implantable device according to claim 5, wherein said dopamine agonist is apomorphine.

Claim 7 (Original): An implantable device according to claim 1, wherein the sustained period of time is at least about 3 months.

Claim 8 (Canceled)

Claim 9 (Original): An implantable device according to claim 8, comprising dimensions of about 2 to about 3 mm in diameter and about 2 to about 3 cm in length.

Claim 10 (Currently Amended): An implantable device according to claim 9, wherein said implantable device releases about 0.1 to about 10 mg of dopamine agonist per day *in vitro* [[at steady state]].

Claim 11 (Withdrawn): An implantable device according to claim 1, further comprising an anti-inflammatory agent encapsulated within said matrix.

Claim 12 (Withdrawn): An implantable device according to claim 11, wherein said anti-inflammatory agent is a steroid.

Claim 13 (Withdrawn): An implantable device according to claim 11, wherein said anti-inflammatory agent is a nonsteroidal anti-inflammatory drug ("NSAID").

Claim 14 (Withdrawn): An implantable device according to claim 11, wherein said anti-inflammatory agent is an antihistamine.

Claim 15 (Original): An implantable device according to claim 1, further comprising an antioxidant encapsulated within said matrix.

Claim 16 (Currently Amended): An implantable device for administration of a dopamine agonist to a mammal in need thereof, comprising a dopamine agonist that binds to one or more dopamine receptor subgroups and a biocompatible, nonerodible polymeric matrix,

wherein said dopamine agonist is encapsulated within said matrix,  
wherein the implantable device is produced by an extrusion process,  
wherein the implantable device is uncoated, and

wherein when said implantable device is subcutaneously implanted in a mammal, said dopamine agonist is continuously released *in vivo* over a sustained period of time through pores that open to the surface of said matrix at a rate of at least about 0.1 mg of dopamine agonist per day at steady state.

Claim 17 (Original): An implantable device according to claim 16, wherein the polymeric matrix comprises EVA.

Claim 18 (Original): An implantable device according to claim 17, wherein said EVA comprises 33% vinyl acetate.

Claim 19 (Original): An implantable device according to claim 16, comprising about 10 to about 85% dopamine agonist.

Claim 20 (Original): An implantable device according to claim 16, wherein said dopamine agonist is selected from the group consisting of apomorphine, lisuride, pergolide, bromocriptine, pramipexole, ropinerole, and rotigotine.

Claim 21 (Withdrawn): An implantable device according to claim 20, wherein said dopamine agonist is apomorphine.

Claim 22 (Original): An implantable device according to claim 16, wherein the sustained period of time is at least about 3 months.

Claim 23 (Canceled)

Claim 24 (Withdrawn): An implantable device according to claim 16, further comprising an anti-inflammatory agent encapsulated within said matrix.

Claim 25 (Withdrawn): An implantable device according to claim 24, wherein said anti-inflammatory agent is a steroid.

Claim 26 (Withdrawn): An implantable device according to claim 24, wherein said anti-inflammatory agent is a NSAID.

Claim 27 (Withdrawn): An implantable device according to claim 24, wherein said anti-inflammatory agent is an antihistamine.

Claim 28 (Previously presented): An implantable device according to claim 16, further comprising an antioxidant encapsulated within said matrix.

Claim 29 (Withdrawn): A method for administration of a dopamine agonist to a mammal in need thereof, the method comprising administering at least one implantable device subcutaneously,

wherein each of said at least one implantable devices comprises a dopamine agonist encapsulated within a biocompatible, nonerodible polymeric matrix,

wherein said dopamine agonist is continuously released *in vivo* from each of said at least one implantable devices over a sustained period of time through pores that open to the surface of said matrix at a rate that results in a plasma level of at least about 0.01 ng/ml at steady state.

Claim 30 (Withdrawn): A method according to claim 29, wherein said at least one implantable device comprises a multiplicity of individual implantable devices, and wherein the combination of said implantable devices continuously releases dopamine agonist *in vivo* over a sustained period of time at a rate that results in a plasma level of at least about 0.05 ng/ml at steady state.

Claim 31 (Withdrawn): A method according to claim 29, wherein the polymeric matrix comprises EVA.

Claim 32 (Withdrawn): A method according to claim 31, wherein said EVA comprises about 33% vinyl acetate.

Claim 33 (Withdrawn): A method according to claim 29, wherein each of said at least one implantable devices comprises at about 10 to about 85% dopamine agonist.

Claim 34 (Withdrawn): A method according to claim 33, wherein said dopamine agonist is selected from the group consisting of apomorphine, lisuride, pergolide, bromocriptine, pramipexole, ropinerole, and rotigotine.

Claim 35 (Withdrawn): A method according to claim 34, wherein said dopamine agonist is apomorphine.

Claim 36 (Withdrawn): A method according to claim 29, wherein said mammal has Parkinson's disease.

Claim 37 (Withdrawn): A method according to claim 29, wherein said mammal has toxin- or disease-induced parkinsonism.

Claim 38 (Withdrawn): A method according to claim 29, wherein said mammal has a condition selected from the group consisting of erectile dysfunction and restless leg syndrome.

Claim 39 (Withdrawn): A method according to claim 29, wherein the sustained period of time is at least about 3 months.

Claim 40 (Withdrawn): A method according to claim 29, wherein each of said at least one implantable devices is produced by an extrusion process.

Claim 41 (Withdrawn): A method according to claim 40, wherein each implantable device comprises dimensions of about 2 to about 3 mm in diameter and about 2 to about 3 cm in length.

Claim 42 (Withdrawn): A method according to claim 41, wherein each implantable device releases at least about 0.1 mg of dopamine agonist per day *in vitro*.

Claim 43 (Withdrawn): A method according to claim 29, wherein each of said at least one implantable devices is subcutaneously implanted at a site selected from the group consisting of the upper arm, the back, and the abdomen.

Claim 44 (Withdrawn): A method according to claim 29, further comprising administration of an anti-inflammatory agent.

Claim 45 (Withdrawn): A method according to claim 44, wherein said anti-inflammatory agent is encapsulated in at least one of said at least one implantable devices.

Claim 46 (Withdrawn): A method according to claim 44, wherein said anti-inflammatory agent is encapsulated within a biocompatible, nonerodible polymeric matrix

that does not comprise said dopamine agonist, and wherein said method comprises administration of said polymeric matrix comprising said anti-inflammatory agent subcutaneously.

Claim 47 (Withdrawn): A method according to claim 44, wherein said anti-inflammatory agent is administered via a route selected from the group consisting of local injection, systemic injection, subcutaneous injection, and oral administration.

Claim 48 (Withdrawn): A method according to claim 44, wherein said at least one implantable device further comprises an antioxidant.

Claim 49 (Currently Amended): A kit comprising at least one implantable device comprising a dopamine agonist that binds to one or more dopamine receptor subgroups encapsulated within a biocompatible, nonerodible polymeric matrix, wherein said at least one implantable device is produced by an extrusion process, wherein said at least one implantable device is uncoated, and wherein when said at least one implantable device is implanted subcutaneously in a mammal, said dopamine agonist is continuously released *in vivo* from each of said at least one implantable devices over a sustained period of time through pores that open to the surface of said matrix at a rate that results in a steady state plasma level of at least about 0.01 ng/ml [[at steady state]] for the sustained period of time and instructions for use in a method of administration of a dopamine agonist to a mammal in need thereof.

Claim 50 (Original): A kit according to claim 49, wherein said at least one implantable device comprises a multiplicity of individual implantable devices, and wherein when the combination of said implantable devices is implanted subcutaneously in a mammal, said implantable devices continuously release dopamine agonist *in vivo* over a sustained period of time at a rate that results in a plasma level of at least about 0.05 ng/ml at steady state.

Claim 51 (Currently Amended): A kit according to claim 49, wherein said at least one implantable device releases dopamine agonist at a rate of at least about 0.1 mg per day *in vitro*.

Claim 52 (Previously presented): A kit according to claim 49, wherein the polymeric matrix in each of said implantable devices comprises EVA.

Claim 53 (Original): A kit according to claim 52, wherein said EVA comprises about 33% vinyl acetate.

Claim 54 (Original): A kit according to claim 49, wherein each of said implantable devices comprises about 10 to about 85% dopamine agonist.

Claim 55 (Original): A kit according to claim 54, wherein said dopamine agonist is selected from the group consisting of apomorphine, lisuride, pergolide, bromocriptine, pramipexole, ropinerole, and rotigotine.

Claim 56 (Withdrawn): A kit according to claim 55, wherein said dopamine agonist is apomorphine.

Claim 57 (Withdrawn): A kit according to claim 49, wherein the at least one implantable device further comprises an anti-inflammatory agent, and said anti-inflammatory agent is encapsulated in at least one of said at least one implantable device.

Claim 58 (Currently Amended): A kit according to claim 49, wherein the at least one implantable device further ~~comprising~~ comprises an anti-inflammatory agent, and said anti-inflammatory agent is encapsulated within a biocompatible, nonerodible polymeric matrix that does not comprise said dopamine agonist.



Claim 59 (Previously presented): An implantable device according to claim 5, wherein said dopamine agonist is lisuride.

Claim 60 (Previously presented): An implantable device according to claim 20, wherein said dopamine agonist is lisuride.

Claim 61 (Previously presented): A kit according to claim 55, wherein said dopamine agonist is lisuride.

Claim 62 (New): An implantable device according to claim 1, wherein said implantable device is washed.

Claim 63 (New): An implantable device according to claim 1, wherein the steady state plasma level is about 0.01 ng/ml to about 10 ng/ml.

Claim 64 (New): An implantable device according to claim 16, wherein said implantable device is washed.

Claim 65 (New): An implantable device according to claim 16, wherein the release of the dopamine agonist results in a steady state plasma level of at least about 0.01 ng/ml for the sustained period of time.

Claim 66 (New): An implantable device according to claim 65, wherein the steady state plasma level is about 0.01 ng/ml to about 10 ng/ml.

Claim 67 (New): An implantable device according to claim 16, comprising dimensions of about 2 to about 3 mm is diameter and about 2 to about 3 cm in length.

Claim 68 (New): A kit according to claim 49, wherein the sustained period of time is at least about 3 months.

Claim 69 (New): A kit according to claim 49, wherein said at least one implantable device comprises dimensions of about 2 to about 3 mm in diameter and about 2 to about 3 cm in length.

Claim 70 (New): A kit according to claim 49, wherein said at least one implantable device is washed.

Claim 71 (New): A kit according to claim 49, wherein the steady state plasma level is about 0.01 ng/ml to about 10 ng/ml.

Claim 72 (New): An implantable device for administration of a dopamine agonist to a mammal in need thereof, comprising a dopamine agonist that binds to one or more dopamine receptor subgroups and a biocompatible, nonerodible polymeric matrix, wherein said dopamine agonist is encapsulated within said matrix, and wherein when said implantable device is implanted subcutaneously in said mammal, said dopamine agonist is continuously released *in vivo* over a sustained period of time through pores that open to the surface of said matrix at a rate that results in a steady state plasma level of at least about 0.01 ng/ml for the sustained period of time, and wherein the sustained period of time is at least about 3 months.

Claim 73 (New): An implantable device according to claim 72, wherein the polymeric matrix comprises ethylene vinyl acetate copolymer (EVA).

Claim 74 (New): An implantable device according to claim 72, wherein said EVA comprises about 33% vinyl acetate.

Claim 75 (New): An implantable device according to claim 72, comprising about 10 to about 85% dopamine agonist.

Claim 76 (New): An implantable device according to claim 72, wherein said dopamine agonist is selected from the group consisting of apomorphine, lisuride, pergolide, bromocriptine, pramipexole, ropinerole, and rotigotine.

Claim 77 (New): An implantable device according to claim 72, wherein said dopamine agonist is lisuride.

Claim 78 (New): An implantable device according to claim 72, comprising dimensions of about 2 to about 3 mm in diameter and about 2 to about 3 cm in length.

Claim 79 (New): An implantable device according to claim 72, wherein said implantable device releases about 0.1 to about 10 mg of dopamine agonist per day *in vitro*.

Claim 80 (New): An implantable device according to claim 72, further comprising an antioxidant encapsulated within said matrix.

Claim 81 (New): An implantable device according to claim 72, wherein the implantable device is washed.

Claim 82 (New): An implantable device according to claim 72, wherein the implantable device is produced by an extrusion process.

Claim 83 (New): An implantable device according to claim 72, wherein the implantable device is uncoated.

Claim 84 (New): An implantable device according to claim 72, wherein the steady state plasma level is about 0.01 ng/ml to about 10 ng/ml.

Claim 85 (New): An implantable device for administration of a dopamine agonist to a mammal in need thereof, consisting essentially of a dopamine agonist that binds to one or more dopamine receptor subgroups, a biocompatible, nonerodible polymeric matrix, and optionally an antioxidant,

wherein said dopamine agonist is encapsulated within said matrix, and

wherein when said implantable device is implanted subcutaneously in said mammal, said dopamine agonist is continuously released *in vivo* over a sustained period of time through pores that open to the surface of said matrix at a rate that results in a steady state plasma level of at least about 0.01 ng/ml for the sustained period of time.

Claim 86 (New): An implantable device for administration of a dopamine agonist to a mammal in need thereof, comprising a dopamine agonist that binds to one or more dopamine receptor subgroups and a biocompatible, nonerodible polymeric matrix,

wherein said dopamine agonist is encapsulated within said matrix,

wherein the implantable device is produced by an extrusion process,

wherein the implantable device is uncoated, and

wherein when said implantable device is implanted subcutaneously in said mammal, said dopamine agonist is continuously released *in vivo* over a sustained period of time through pores that open to the surface of said matrix at a rate that results in a steady state plasma level of at least about 0.01 ng/ml for the sustained period of time, wherein the sustained period of time is at least about 3 months.

Claim 87 (New): An implantable device for administration of a dopamine agonist to a mammal in need thereof, comprising a dopamine agonist that binds to one or more dopamine receptor subgroups and a biocompatible, nonerodible polymeric matrix,

wherein the implantable device comprises about 10 to about 85% dopamine agonist,

wherein said dopamine agonist is encapsulated within said matrix,  
wherein the implantable device is produced by an extrusion process,  
wherein the implantable device is uncoated,  
wherein the implantable device is washed,  
wherein said dopamine agonist is lisuride,  
wherein said polymer matrix comprises EVA, and said EVA comprises about 33% vinyl acetate, and

wherein when said implantable device is implanted subcutaneously in said mammal, said dopamine agonist is continuously released *in vivo* over a sustained period of time through pores that open to the surface of said matrix at a rate that results in a steady state plasma level of about 0.01 ng/ml to about 10 ng/ml for the sustained period of time, wherein the sustained period of time is at least about 3 months.